

Dkt. 2048/57906-E/JPW/AJD/BWSL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: William C. Olson and Paul J. Maddon

Serial No.: 10/763,545 Examiner:

Filed: January 23, 2004 Group Art Unit:

For: SYNERGISTIC INHIBITION OF HIV-1 FUSION AND

ATTACHMENT, COMPOSITIONS AND ANTIBODIES THERETO

1185 Avenue of the Americas New York, NY 10036 August 12, 2004

Commissioner for Patents P.O. Box 1450
Alexandria VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. \$1.56, applicants direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (Exhibit A), and certain of which are attached hereto as Exhibits 1-3:

- Allaway, G.P., K.L. Davis-Bruno, B.A. Beaudry, E.B. Garcia, E.L. Wong, A.M. Ryder, K.W. Hasel, M.C. Gauduin, R.A. Koup, J.S. McDougal and P.J. Maddon. 1995. Expression and characterization of CD4-IgG2, a novel heterotetramer that neutralizes primary HIV type 1 isolates. AIDS Res Hum Retroviruses 11: 533-539;
- 2. Allaway, G.P., A.M. Ryder, G.A. Beaudry and P.J. Maddon. 1993. Synergistic inhibition of HIV-1 envelope-mediated cell fusion by CD4-based molecules in combination with antibodies to gp120 or gp41. AIDS Res. Hum. Retroviruses 9: 581-587;
- Amara, A., S.L. Gall, O. Schwartz, J. Salamero, M. Montes,
 P. Loetscher, M. Baggiolini, J.L. Virelizier and F.

Serial No.: 10/763,545

Filed: January 23, 2004

Page 2

Arenzana-Seisdedos. 1997. HIV coreceptor downregulation as antiviral principle: SDF-la-dependent internalization of the chemokine receptor CXCR4 contributes to inhibition of HIV replication. J. Exp. Med. 186: 139-146;

- 4. Berger, E.A. 1997. HIV entry and tropism: the chemokine receptor connection. AIDS 11 (suppl A): S3-S16;
- 5. Bieniasz, P.D., R.A. Fridell, I. Aramori, S.S.G. Ferguson, M.C. Caron and B.R. Cullen. 1997. HIV-1-induced cell fusion is mediated by multiple regions within both the viral envelope and the CCR5 co-receptor. EMBO J. 16: 2599-2609;
- 6. Brelot, A., N. Heveker, O. Pleskoff, N. Sol and M. Alizon. 1997. Role of the first and third extracellular domains of CXCR4 in human immunodeficiency virus coreceptor activity. J. Virol. 71: 4744-4751;
- 7. Chan, D.C. and P.S. Kim. 1998. HIV entry and its inhibition. Cell 93: 681-684;
- 8. Connor, R.I., K.E. Sheridan, D. Ceradini, S. Choe and N.R. Landau. 1997. Change in co-receptor use correlates with disease progression in HIV-1 infected individuals. J. Exp. Med. 185: 621-628;
- 9. Crump, M.P., J.H. Gong, P. Loetscher, K. Rajarathnam, A. Amara, F. Arenzana-Seisdedos, J.L. Virelizier, M. Baggiolini, B.D. Sykes and I. Clark-Lewis. 1997. Solution structure and basis for functional activity of stromal-cell derived factor-1; disassociation of CXCR4 activation from binding and inhibition of HIV-1. EMBO J. 16: 6996-7007;
- 10. Dalgleish, A.G., P.C.L. Beverly, P.R. Clapham, D.H. Crawford, M.F. Greaves and R.A. Weiss. 1984. The CD4 (T4)

Serial No.: 10/763,545

Filed: January 23, 2004

Page 3

antigen is an essential component of the receptor for the AIDS retrovirus. Nature 312: 763-766;

11. Donzella, G.A., D. Schols, S.W. Lin, J.A. Este, K.A. Nagashima, P.J. Maddon, G.P. Allaway, T.P. Sakmar, G. Henson, E.D. Clercq and J.P. Moore. 1998. AMD3100, a small molecule inhibitor of HIV-1 entry via the CXCR4 coreceptor. Nat. Med. 4: 72-77;

- 12. Doranz, B.J., K. Grovit-Ferbas, M.P. Sharron, S.H. Mao,
 M.B. Goetz, E.S. Daar, R.W. Doms and W.A. O'Brien. 1997. A
 small molecule inhibitor directed against the chemokine
 receptor CXCR4 prevents its use as an HIV-1 co-receptor.
 J. Exp. Med. 186: 1395-1400;
- Doranz, B.J., Z.-H. Lu, J. Rucker, T.-Y. Zhang, M. Sharron, Y.-H. Cen, Z.-X. Wang, H.-H. Guo, J.-G. Du, M.A. Accavitti, R.W. Doms and S.C. Peiper. 1997. Two distinct CCR5 domains can mediate co-receptor usage by human immunodeficiency virus type 1. J. Virol. 71: 6305-6314;
- 14. Dragic, T., V. Litwin, G.P. Allaway, S.R. Martin, Y. Huanh, K.A. Nagashima, C. Cayanan, P.J. Maddon, R.A. Koup, J.P. Moore and W.A. Paxton. 1996. HIV-1 entry into CD4+ cells is mediated by the chemokine receptor CC-CKR-5. Nature 381: 667-673;
- 15. Hill, C.M., D. Kwon, M. Jones, C.B. Davis, S. Marmon, B.L. Daugherty, J.A. DeMartino, M.S. Springer, D. Unutmaz and D.R. Littman. 1998. The amino terminus of human CCR5 is required for its function as a receptor for diverse human and simian immunodeficiency virus envelope glycoproteins. Virology 248: 357-371;

Serial No.: 10/763,545

Filed: January 23, 2004

Page 4

16. Kwong, P.D., R. Wyatt, J. Robinson, R.W. Sweet, J. Sodroski and W.A. Hendrickson. 1998. Structure of an HIV gp120 envelope glycoprotein in complex with the CD4 receptor and a neutralizing human antibody. Nature 393: 648-659;

- 17. Laal, S., S. Burda, M.K. Gorny, S. Karwowska, A. Buchbinder and S. Zolla-Pazner. 1994. Synergistic neutralization of human immunodeficiency virus type 1 by combinations of human monoclonal antibodies. J. Virol. 68: 4001-4008;
- 18. Li, A., H. Katinger, M.R. Posner, L. Cavacini, S. Zolla-Pazner, M.K. Gorny, J. Sodroski, T.C. Chou, T.W. Baba and R.M. Ruprecht. 1998. Synergistic neutralization of simian-human immunodeficiency virus SHIV-vpu+ by triple and quadruple combinations of human monoclonal antibodies and hig-titer antihuman immunodeficiency virus type 1 immunoglobulins. J. Virol. 72: 3235-3240;
- 19. Mack, M., B. Luckow, P.J. Nelson, J. Cihak, G. Simmons, P.R. Clapham, N. Signoret, M. Marsh, M. Stangassinger, F. Borlat, T.N.C. Wells, D. Schlondorff and A.E.I. Proudfoot. 1998. Aminooxypentane-RANTES induces CCR5 internalization but inhibits recycling: a novel inhibitory mechanisms of HIV infectivity. J. Exp. Med. 187: 1215-1224;
- 20. McKnight, A., D. Wilkinson, G. Simmons, S. Talbot, L. Picard, M. Ahuja, M. Marsh, J.A. Hoxie and P.R. Clapham. 1997. Inhibition of human immunodeficiency virus fusion by a monoclonal antibody to a coreceptor (CXCR3) is both cell type and virus strain dependent. J. Virol. 71: 1692-1696;
- 21. Strizki, J.M., J. Davis-Turner, R.G. Collman, J. Hoxie and F. Gonzalez-Scarano. 1997. A monoclonal antibody (12G5) directed against CXCR4 inhibits infection with the dualtropic human immunodeficiency virus type 1 isolate HIV-1

Serial No.: 10/763,545

Filed: January 23, 2004

Page 5

89.6 but not the T-tropic isolate HIV-1 HxB. J. Virol. 71: 5678-5683;

- 22. Trkola, A., T. Dragic, J. Arthos, J. Binley, W.C. Olson, G.P. Allaway, C. Cheng-Mayer, J. Robinson, P.J. Maddon and J.P. Moore. 1996. CD4-dependent, antibody sensitive interactions between HIV-1 and its co-receptor CCR-5. Nature 384: 184-187;
- 23. Vijh-Warrier, S., A. Pinter, W.J. Honnen and S.A. Tilley. 1996. Synergistic neutralization of human immunodeficiency virus type 1 by a chimpanzee monoclonal antibody against the V2 domain of gp120 in combination with monoclonal antibodies against the V3 loop and the CD4-binding site. J. Virol. 70: 4466-4473;
- 24. Wu, L., G. LaRosa, N. Kassam, C.J. Gordon, H. Heath, N. Ruffing, H. Chen, J. Humblias, M. Samson, M. Parmentier, J.P. Moore and C.R. Mackay. 1997. Interaction of chemokine receptor CCR5 with its ligands: multiple domains for HIV-1 gp120 binding and a single domain for chemokine binding. J. Exp. Med. 186: 1373-1381;
- 25. Ylisastigui, L., J.J. Vizzavona, E. Drakopoulou, P. Paindavoine, C.F. Calvo, M. Parmentier, J.C. Gluckman, C. Vita and A. Benjouad. 1998. Synthetic full length and truncated RANTES inhibit HIV-1 infection of primary macrophages. AIDS 12: 977-984;
- 26. Tilley, S. A., W.J. Honnen, S. Warrier, M.E. Racho, T.C. Chou, M. Girard, E. Muchmore, M. Hilgartner, D.D. Ho, M.S.C. Fung and A. Pinter. 1991. Potent neutralization of HIV-1 by human and chimpanzee monoclonal antibodies directed against three distinct epitope clusters of gp120. Sixieme Colloque Des Cent Gardes, pp. 211-216;

Serial No.: 10/763,545

Filed: January 23, 2004

Page 6

27. Tilley, S.A., W.J. Honnen, M.E. Racho, T.C. Chou and A. Pinter. 1992. Synergistic neutralization of HIV-1 by human monoclonal antibodies against the V3 loop and the CD4-binding site of gp120. AIDS Res. Hum. Retroviruses 80: 461-467;

- 28. Choe, H., M. Farzan, Y. Sun, N. Sullivan, B. Rollins, P.D. Ponath, L. Wu, C.R. Mackay, G. LaRosa, W. Newman, N. Gerard, C. Gerard and J. Sodroski. 1996. The beta-chemokine receptors CCR3 and CCR5 facilitate infection by primary HIV-1 isolates. Cell 85: 1135-1148;
- 29. Doranz, B.J., J. Rucker, Y. Yi, R. Smyth, M. Samson, S.C. Peiper, M. Parmentier, R.G. Collman and R.W. Doms. 1996. A dual-tropic primary HIV-1 Isolate that uses fusin and beta-chemokine receptors CKR-5, CKR-3, and CKR-2b as fusion cofactors. Cell 85: 1149-1158;
- 30. Deng, H., R. Liu, W. Ellmeier, S. Choe, D. Unutmaz, M. Burkhart, P.D. Marzio, S.Marmon, R.E. Sutton, C.M. Hill, C.B. Davis, S.C. Peiper, T.J. Schall, D.R. Littman and N.R. Landau. 1996. Identification of a major co-receptor for primary isolates of HIV-1. Nature 381: 661-666;
- 31. Feng, Y., C.C. Broder, P.E. Kennedy and E.A. Berger. 1996. HIV-1 entry cofactor: functional cDNA cloning of a seventransmembrane, G protein-coupled receptor. Science 272: 872-877;
- 32. Fradd, F. and M.E. Mary. 1989. AIDS Vaccines: An Investor's Guide by Shearman Lehaman Hutton. Page 10 (Fig. 2);
- 33. De Rossi, A., M. Pasti, F. Mummano, M. Panozzo, M. Dettin,

Serial No.: 10/763,545

Filed: January 23, 2004

Page 7

C. Di Bello and L. Chieco-Bianchi. 1995. Synthetic peptides from the principle neutralizing domain of human immunodeficiency virus type 1 (HIV-1) enhance HIV-1 infection through a CD4-dependent mechanism. Virology 184: 187-196;

- 34. U.S. Patent No. 6,528,625, issued March 4, 2003 to Lijun Wu et al.;
- 35. Yi Li et al., U.S. Serial No. 10/232,686, filed September 3, 2002, U.S. Publication No. 2003/0023044, published January 30, 2003;
- 36. Craig A. Rosen et al., U.S. Serial No. 09/779,879, filed February 9, 2001, U.S. Publication No. 2002/0048786, published April 25, 2002;
- 37. Craig A. Rosen et al., U.S. Serial No. 09/779,880, filed February 9, 2001, U.S. Publication No. 2002/0061834, published May 23, 2002;
- 38. Yi Li et al., U.S. Serial No. 09/195,662, filed November 18, 1998, U.S. Publication No. 2002/0076745, published June 20, 2002;
- 39. Yi Li et al., U.S. Serial No. 09/339912, filed June 25, 1999, U.S. Patent Application Publication No. US 2002/0099176, published July 25, 2002;
- 40. Michel Samson et al., U.S. Serial No. 09/938,719, filed August 24, 2001, U.S. Publication No. 2002/0106742, published August 8, 2002;
- 41. Michel Samson et al., U.S. Serial No. 09/939,226, filed

Serial No.: 10/763,545

Filed: January 23, 2004

Page 8

August 24, 2001, U.S. Publication No. 2002/0110805, published August 15, 2002;

- 42. Michel Samson et al., U.S. Serial No. 09/938,703, filed August 24, 2001, U.S. Publication No. 2002/0110870, published August 15, 2002;
- 43. Yi Li et al., U.S. Serial No. 09/502783, filed February 11, 2000, U.S. Publication No. 2002/0132269, published September 19, 2002;
- 44. Co, M.S., M. Deschamps, R.J. Whitley and C. Queen. 1991. Humanized antibodies for antiviral therapy. Proc. Natl. Acad. Sci. U.S.A. 88: 2869-2873;
- 45. Trkola, A., T.J. Ketas, K.A. Nagashima, L. Zhao, T. Cilliers, L. Morris, J.P. Moore, P.J. Maddon and W.C. Olson. 2001. Potent, broad-spectrum inhibition of human immunodeficiency virus type 1 by the CCR5 monoclonal antibody PRO 140. J. Virol. 75: 579-588;
- 46. Olson, W.C., G.E. Rabut, K.A. Nagashima, D.N. Tran, D.J. Anselma, S.P. Monard, J.P. Segal, D.A. Thompson, F. Kajumo, Y. Guo, J.P. Moore, P.J. Maddon and T. Dragic. 1999. Differential inhibition of human immunodeficiency virus type 1 fusion, gp120 binding, and CC-chemokine activity by monoclonal antibodies to CCR5. J. Virol. 73: 4145-4155;
- 47. Parren, P.W., P.A. Marx, A.J. Hessell, A. Luckay, J. Harouse, C. Cheng-Mayer, J.P. Moore and D.R. Burton. 2001. Antibody protects macaques against vaginal challenge with a pathogenic R5 simian/human immunodeficiency virus at serum levels giving complete neutralization in vitro. J. Virol. 75: 8340-8347;

Serial No.: 10/763,545

Filed: January 23, 2004

Page 9

48. Lehner, T., C. Doyle, Y. Wang, K. Babaahmady, T. Whittall, L. Tao, L. Bergmeier and C. Kelly. 2001. Immunogenicity of the extracellular domains of C-C chemokine receptor 5 and the in vitro effects on simian immunodeficiency virus or HIV infectivity. J. Immunol. 166: 7446-7455;

- 49. Wu, L., W.A. Paxton, N. Kassam, N. Ruffing, J.B. Rottman, N. Sullivan, H. Choe, J. Sodroski, W. Newman, R.A. Koup and C.R. Mackay. 1997. CCR5 levels and expression pattern correlate with infectability by macrophage-tropic HIV-1, in vitro. J. Exp. Med. 185: 1681-1691;
- 50. William C. Olson and Paul J. Maddon, U.S. Serial No. 09/594,983, filed June 15, 2000;
- 51. William C. Olson and Paul J. Maddon, U.S. Serial No. 09/828,615, filed April 6, 2001, U.S. Publication No. 2002/0146415 A1, published October 10, 2002;
- 52. William C. Olson and Paul J. Maddon, U.S. Serial No. 10/081,128, filed February 22, 2002;
- 53. William C. Olson and Paul J. Maddon, U.S. Serial No. 10/116,797, filed April 5, 2002, U.S. Publication No. 2003/0044411 A1, published March 6, 2003;
- 54. William C. Olson et al., U.S. Serial No. 10/371,483, filed February 21, 2003, U.S. Publication No. 2003/0228306 A1, published December 11, 2003;
- 55. PCT International Application No. PCT/US97/19661, filed October 27, 1997, International Publication No. WO 98/18826, published May 7, 1998;

Serial No.: 10/763,545

Filed: January 23, 2004

Page 10

56. Chen Z., P. Zhou, D.D. Ho, N.R. Landau and P.A. Marx. 1997. Genetically divergent strains of simian immunodeficiency virus use CCR5 as a coreceptor for entry. J. Virol. 71: 2705-2714;

- 57. William C. Olson and Paul J. Maddon, U.S. Provisional Application No. 60/282,380, filed April 6, 2001;
- 58. William C. Olson and Paul J. Maddon, U.S. Provisional Application No. 60/358,886, filed February 22, 2002;
- 59. U.S. Patent No. 6,107,019, issued August 22, 2000 to G.P. Allaway et al.;
- 60. U.S. Patent No. 6,344,545 B1, issued February 5, 2002 to G.P. Allaway et al.;
- 61. U.S. Patent No. 6,548,636 B2, issued April 15, 2003 to T. Dragic and W.C. Olson;
- 62. Pending claims in G.P. Allaway et al., U.S. Serial No. 09/888,938, filed June 25, 2001;
- 63. Allowed claims in T. Dragic and W.C. Olson, U.S. Serial No. 10/323,314, filed December 19, 2002;
- 64. G.P. Allaway et al., U.S. Serial No. 08/627,684, filed April 2, 1996 (now abandoned);
- 65. G.P. Allaway et al., U.S. Provisional Application No. 60/014,532, filed April 2, 1996;
- 66. G.P. Allaway et al., U.S. Serial No. 08/663,616, filed June

Serial No.: 10/763,545

Filed: January 23, 2004

Page 11

14, 1996 (now abandoned);

- 67. G.P. Allaway et al., U.S. Provisional Application No. 60/019,715, filed June 14, 1996;
- 68. G.P. Allaway et al., U.S. Serial No. 08/673,682, filed June 25, 1996 (now abandoned);
- 69. G.P. Allaway et al., U.S. Serial No. 08/665,090, filed June 14, 1996 (now abandoned);
- 70. G.P. Allaway et al., U.S. Provisional Application No. 60/019,941, filed June 14, 1996;
- 71. G.P. Allaway et al., U.S. Serial No. 08/874,570, filed June 13, 1997 (now abandoned);
- 72. G.P. Allaway et al., U.S. Serial No. 08/874,618, filed June 13, 1997 (now abandoned);
- 73. Pending claims in G.P. Allaway et al., U.S. Serial No. 09/724,105, filed November 28, 2000;
- 74. Pending claims in G.P. Allaway et al., U.S. Serial No. 09/852,238, filed May 9, 2001 (published May 6, 2004 as U.S. Patent Application Publication No. 2004/0086528 A1);
- 75. W.C. Olson and P.J. Maddon, U.S. Serial No. 09/212,793, filed December 16, 1998 (now abandoned);
- 76. W.C. Olson and P.J. Maddon, U.S. Provisional Application No. 60/112,532, filed December 16, 1998;
- 77. W.C. Olson and P.J. Maddon, U.S. Serial No. 09/464,902,

Serial No.: 10/763,545

Filed: January 23, 2004

Page 12

filed December 16, 1999;

- 78. W.C. Olson et al., U.S. Serial No.09/663,219, filed September 15, 2000;
- 79. W.C. Olson et al., U.S. Provisional Application No. 60/266,738, filed February 6, 2001;
- 80. W.C. Olson and P.J. Maddon, U.S. Patent Application Publication No. 2002/0146415 Al, published October 10, 2002;
- 81. W.C. Olson and P.J. Maddon, U.S. Provisional Application No. 60/282,380, filed April 6, 2001;
- 82. W.C. Olson et al., U.S. Patent Application Publication No. 2002/0106374 Al, published August 8, 2002;
- 83. W.C. Olson and P.J. Maddon, U.S. Serial No. 10/081,128, filed February 22, 2002 (now abandoned);
- 84. W.C. Olson and P.J. Maddon, U.S. Provisional Application No. 60/358,886, filed February 22, 2002;
- 85. William C. Olson and Paul J. Maddon, U.S. Publication No. 2003/0044411 A1, published March 6, 2003;
- 86. T. Dragic and W.C. Olson, U.S. Patent Application Publication No. 2003/0092632 Al, published May 15, 2003;
- 87. W.C. Olson et al., U.S. Patent Application Publication No. 2003/0228306 A1, published December 11, 2003;
- 88. Pending claims in W.C. Olson and P.J. Maddon, U.S. Serial

Serial No.: 10/763,545

Filed: January 23, 2004

Page 13

No. 10/763,545, filed January 23, 2004;

- 89. Pending claims in G.P. Allaway et al., U.S. Serial No. 09/460,216, filed December 13, 1999;
- 90. PCT International Application Publication No. WO 96/41020, published December 19, 1996;
- 91. PCT International Application Publication No. WO 97/26009, published July 24, 1997;
- 92. PCT International Application Publication No. WO 97/37005, published October 27, 1997;
- 93. PCT International Application Publication No. WO 97/47319, published January 7, 1998;
- 94. PCT International Application Publication No. WO 98/56421, published December 17, 1998;
- 95. PCT International Application Publication No. WO 00/35409, published June 22, 2000;
- 96. PCT International Application Publication No. WO 01/64710, published September 7, 2001;
- 97. PCT International Application Publication No. WO 02/22077, published March 21, 2002;
- 98. PCT International Application Publication No. WO 02/068608, published September 6, 2002;
- 99. PCT International Application Publication No. WO 02/083172, published October 24, 2002;

Serial No.: 10/763,545

Filed: January 23, 2004

Page 14

100. PCT International Application Publication No. WO 03/072766, published September 4, 2003;

- 101. Rudikoff, S. Giusti, A. M., Cook, W. D., Scharff M. D., 1982. Single amino acid substitution altering antigen-binding specificity. Proc. Natl. Acad. Sci. 79: 1979-1983
- 102. U.S. Patent No. 5,994,515, issued November 30, 1999 to J.A. Hoxie (Exhibit 1);
- 103. U.S. Patent No. 6,759,519 issued July 6, 2004 to Y. Li and
 S. M. Ruben (Exhibit 2); and
- 104. PCT International Application Publication No. WO 97/49424, published December 31, 1997 (Exhibit 3).

The Examiner is respectfully requested to make these references of record in the present application by initialing and returning a copy of the enclosed Form PTO 1449.

The subject application is a continuation of 09/594,983, filed June 15, 2000, which is a continuation-in-part of and claims priority of U.S. Serial No. 09/464,902, filed December 16, 1999. Applicants note that copies of the above-listed references 1-56 were submitted to the Patent Office in Information Disclosure Statements filed in connection with U.S. Serial No. 09/464,902 as follows: references 1-31 on June 19, 2000; references 32 and 33 on June 14, 2001; references 34-49 on September 3, 2003; and references 50-56 on April 12, 2004. Applicants further note that copies of the above-listed references 59-100 were submitted to the Patent Office in an Information Disclosure Statement, filed June 3, 2004, in connection with U.S. Serial No. 09/594,983. The above-listed reference 101 was cited by the Patent Office in a

Serial No.: 10/763,545

Filed: January 23, 2004

Page 15

Notice of References Cited, provided with the April 2, 2004 Office Action in connection with U.S. Serial No. 09/464,902. Accordingly, pursuant to 37 C.F.R. \$1.98(d), copies of these references are not attached hereto since they were previously submitted to or cited by the Patent Office in an application relied upon for an earlier filing date under 35 U.S.C. \$120.

Under 37 C.F.R. §1.98(c), when the disclosures of two or more patents or publications listed in an Information Disclosure Statement are substantively cumulative, a copy of one of the patents or publications or publications may be submitted without copies of the other patents or publications, provided it is stated that these other patents or publications are cumulative. In accordance with 37 C.F.R. §1.98(c), copies of references 57, and 58 listed above are not attached hereto as they contain an identical disclosure to references 51 and 52, respectively, and are thus cumulative.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Applicants:

William C. Olson and Paul J. Maddon

Serial No.:

10/763,545

Filed:

January 23, 2004

Page 16

Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

certify hereby that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450, Alexandria VA 22313-1450

John P. White

-R∕eg. No. 28,678

Date

John R.\White

Registration No. 28,678 Attorney for Applicants Cooper & Dunham, LLP 1185 Avenue of the Americas New York, New York 10036 (212) 278-0400

U.S. Department of Commerce Patent and Trademark Office

Atty. Docket No. Serial No. 57906-E 10/763,545 JPW/AJD/BWSL

Applicant(s)

W. C. Olson and P. J. Maddon

Filing Date January 23, 2004

Art Unit

FORMATION DISCLOSURE CITATION (Use several sheets if necessary)

U.S. PATENT DOCUMENTS

Examiner Initials	Exh No.	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		6 5 2 8 6 2 5	03/04/03	Wu et al.			
		2003/0023044	01/30/03	Li et al.			
		2002/0048786	04/25/02	Rosen et al.			
		2002/0061834	05/23/02	Rosen et al.			
		2002/0076745	06/20/02	Li et al.			

FOREIGN PATENT DOCUMENTS

		D						D - 4 -	C1	Cl	C 1 . 1	Transl	ation
		Doc	ume	nt 19	umb	er		Date	Country	Class	Subclass	Yes	No
	9	8	1	8	8	2	6	05/07/98	PCT		, ,	-	
	9	6	4	1	0	2	0	12/19/96	PCT				
	9	7	2	6	0	0	9	07/24/97	PCT				
	9	7	3	7	0	0	5	10/27/97	PCT				
	9	7	4	7	3	1	9	01/07/98	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

K.W. Hasel, M.C. Gauduin, R.A. Koup, J.S. McDougal and P.J. Maddon. 1995. Expression and characterization of CD4-IgG2, a novel heterotetramer that neutralizes primary HIV type 1 isolates. AIDS Res Hum Retroviruses 11: 533-539; Allaway, G.P., A.M. Ryder, G.A. Beaudry and P.J. Maddon. 1993. Synergistic inhibition of HIV-1 envelope-mediated cell fusion by CD4-based molecules in combination with antibodies to gp120 or gp41. AIDS Res. Hum. Retroviruses 9: 581-587; Amara, A., S.L. Gall, O. Schwartz, J. Salamero, M. Montes, P. Loetscher, M. Baggiolini, J.L. Virelizier and F. Arenzana-Seisdedos. 1997. HIV coreceptor downregulation as antiviral principle: SDF-1a-dependent internalization of the chemokine receptor CXCR4 contributes to inhibition of HIV replication. J. Exp. Med. 186: 139-146; Berger, E.A. 1997. HIV entry and tropism: the chemokine receptor connection. AIDS 11 (Suppl A): S3-S16; Bieniasz, P.D., R.A. Fridell, I. Aramori, S.S.G. Ferguson, M.C. Caron and B.R. Cullen. 1997. HIV-1-induced cell fusion is mediated by multiple regions within both the viral

envelope and the CCR5 co-receptor. EMBO J. 16: 2599-2609;

Allaway, G.P., K.L. Davis-Bruno, B.A. Beaudry, E.B. Garcia, E.L. Wong, A.M. Ryder,

Brelot, A., N. Heveker, O. Pleskoff, N. Sol and M. Alizon. 1997. Role of the first and third extracellular domains of CXCR4 in human immunodeficiency virus coreceptor activity. J. Virol. 71: 4744-4751;

EXAMINER

DATE CONSIDERED

^{*}EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

U.S. Department of Commerce Patent and Trademark Office

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Atty. Docket No. Serial No. 57906-E 10/763,545 JPW/AJD/BWSL

Applicant(s)

W. C. Olson and P. J. Maddon

Filing Date January 23, 2004 Art Unit

U.S. PATENT DOCUMENTS

Examiner Initials	Exh No.	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		2002/0099176	07/25/02	Li et al.			
		2002/0106742	08/08/02	Samson et al.			
		2002/0110805	08/15/02	Samson et al.			
		2002/0110870	08/15/02	Samson et al.			
		2002/0132269	09/19/02	Li et al.			

		D		- 4 NI				D-4-	C	Cl	0.1.1	Tran	slation
		Doc	ume	nt IN	umo	er		Date	Country	Class	Subclass	Yes	No
	9	8	5	6	4	2	1	12/17/98	PCT				
	0	0	3	5	4	0	9	06/22/00	PCT				
	0	1	6	4	7	1	0	09/07/01	PCT				
	0	2	2	2	0	7	7	03/21/02	PCT				
	0 2	0	6	8	6	0	8	09/06/02	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Chan, D.C. and P.S. Kim. 1998. HIV entry and its inhibition. Cell 93: 681-684;

Connor, R.I., K.E. Sheridan, D. Ceradini, S. Choe and N.R. Landau. 1997. Change in coreceptor use correlates with disease progression in HIV-1 infected individuals. J. Exp. Med. 185: 621-628;

Crump, M.P., J.H. Gong, P. Loetscher, K. Rajarathnam, A. Amara, F. Arenzana-Seisdedos, J.L. Virelizier, M. Baggiolini, B.D. Sykes and I. Clark-Lewis. 1997. Solution structure and basis for functional activity of stromal-cell derived factor-1; disassociation of CXCR4 activation from binding and inhibition of HIV-1. EMBO J. 16: 6996-7007;

Dalgleish, A.G., P.C.L. Beverly, P.R. Clapham, D.H. Crawford, M.F. Greaves and R.A. Weiss. 1984. The CD4 (T4) antigen is an essential component of the receptor for the AIDS retrovirus. Nature 312: 763-766;

Donzella, G.A., D. Schols, S.W. Lin, J.A. Este, K.A. Nagashima, P.J. Maddon, G.P. Allaway, T.P. Sakmar, G. Henson, E.D. Clercq and J.P. Moore. 1998. AMD3100, a small molecule inhibitor of HIV-1 entry via the CXCR4 co-receptor. Nat. Med. 4: 72-77;

Doranz, B.J., K. Grovit-Ferbas, M.P. Sharron, S.H. Mao, M.B. Goetz, E.S. Daar, R.W. Doms and W.A. O'Brien. 1997. A small molecule inhibitor directed against the chemokine receptor CXCR4 prevents its use as an HIV-1 co-receptor. J. Exp. Med. 186: 1395-1400;

EXAMINER

DATE CONSIDERED

^{*}EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant,

Atty. Docket No. Serial No. Form PTO-1449 U.S. Department of Commerce 57906-E 10/763,545 Patent and Trademark Office JPW/AJD/BWSL Applicant(s) INFORMATION DISCLOSURE CITATION W. C. Olson and P. J. Maddon (Use several sheets if necessary) Filing Date Art Unit January 23, 2004 U.S. PATENT DOCUMENTS Exh Examiner **Document Number** Class Filing Date Date Name Subclass No. Initials If Appropriate 09 4 3 Olson et al. 06/15/00 2002/0146415 10/10/02 Olson et al. 0 8 1 1 1 2 8 Olson et al. 02/22/02 2003/0044411 03/06/03 Olson et al. 12/11/03 Olson et al. 2003/0228306 FOREIGN PATENT DOCUMENTS Translation **Document Number** Date Country Class Subclass Yes No 0 2 2 10/24/02 **PCT** 0 8 3 1 7 7 2 7 09/04/03 PCT 0.3 0 6 6 PCT 9 4 9 4 2 12/31/97 7 4 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Doranz, B.J., Z.-H. Lu, J. Rucker, T.-Y. Zhang, M. Sharron, Y.-H. Cen, Z.-X. Wang, H.-H. Guo, J.-G. Du, M.A. Accavitti, R.W. Doms and S.C. Peiper. 1997. Two distinct CCR5 domains can mediate co-receptor usage by human immunodeficiency virus type 1. J. Virol. 71: 6305-6314; Dragic, T., V. Litwin, G.P. Allaway, S.R. Martin, Y. Huanh, K.A. Nagashima, C. Cayanan, P.J. Maddon, R.A. Koup, J.P. Moore and W.A. Paxton. 1996. HIV-1 entry into CD4+ cells is mediated by the chemokine receptor CC-CKR-5. Nature 381: 667-673; Hill, C.M., D. Kwon, M. Jones, C.B. Davis, S. Marmon, B.L. Daugherty, J.A. DeMartino, M.S. Springer, D. Unutmaz and D.R. Littman. 1998. The amino terminus of human CCR5 is required for its function as a receptor for diverse human and simian immunodeficiency virus envelope glycoproteins. Virology 248: 357-371; Kwong, P.D., R. Wyatt, J. Robinson, R.W. Sweet, J. Sodroski and W.A. Hendrickson. 1998. Structure of an HIV gp120 envelope glycoprotein in complex with the CD4 receptor and a neutralizing human antibody. Nature 393: 648-659; Laal, S., S. Burda, M.K. Gorny, S. Karwowska, A. Buchbinder and S. Zolla-Pazner. 1994. Synergistic neutralization of human immunodeficiency virus type 1 by combinations of human monoclonal antibodies. J. Virol. 68: 4001-4008;

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

DATE CONSIDERED

EXAMINER

U.S. Department of Commerce Patent and Trademark Office

Atty. Docket No. | Serial No. | 57906-E | 10/763,545 | JPW/AJD/BWSL |

Applicant(s)

INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)

W. C. Olson and P. J. Maddon

Filing Date
January 23, 2004

Art Unit

U.S. PATENT DOCUMENTS

Examiner Initials	Exh No.		Doc	ume	nt N	umb	er		Date	Name	Class	Subclass	Filing Date If Appropriate
		60	2	8	2	3	8	0		Olson et al.			04/06/01
		60	3	5	8	8	8	6	-	Olson et al.			02/22/02
		6	1	0	7	0	1	9	08/22/00	Allaway et al.	-		
		6	3	4	4	5	4	5	02/05/02	Allaway et al.			
		6	5	4	8	6	3	6	04/15/03	Dragic et al.			
	CO	HER	DO	OCU	JMD	ENT	rs (Inc	luding Auth	or, Title, Date, P	ertinen	t Pages, E	tc.)
		Li, A	4., I	H. K	Catin	nger	, M	.R.	Posner, L. C	avacini, S. Zolla-	-Pazner,	M.K. Gor	ny, J. Sodroski,
		T.C.	Ch	ou,	T.V	Ñ. I	3ab	a ar	id R.M. Rup	recht. 1998. Syr	nergistic	neutraliza	tion of simian-
										-vpu+ by triple	_		

human immunodeficiency virus SHIV-vpu+ by triple and quadruple combinations of human monoclonal antibodies and hig-titer antihuman immunodeficiency virus type 1 immunoglobulins. J. Virol. 72: 3235-3240;

Mack, M., B. Luckow, P.J. Nelson, J. Cihak, G. Simmons, P.R. Clapham, N. Signoret, M. Marsh, M. Stangassinger, F. Borlat, T.N.C. Wells, D. Schlondorff and A.E.I. Proudfoot.

1998. Aminooxypentane-RANTES induces CCR5 internalization but inhibits recycling: a novel inhibitory mechanisms of HIV infectivity. J. Exp. Med. 187: 1215-1224; McKnight, A.,D. Wilkinson, G. Simmons, S. Talbot, L. Picard, M. Ahuja, M. Marsh, J.A. Hoxie and P.R. Clapham. 1997. Inhibition of human immunodeficiency virus fusion by a monoclonal antibody to a coreceptor (CXCR3) is both cell type and virus strain dependent.

J. Virol. 71: 1692-1696;

Strizki, J.M., J. Davis-Turner, R.G. Collman, J. Hoxie and F. Gonzalez-Scarano. 1997. A monoclonal antibody (12G5) directed against CXCR4 inhibits infection with the dual-tropic human immunodeficiency virus type 1 isolate HIV-1 89.6 but not the T-tropic isolate HIV-1 HxB. J. Virol. 71: 5678-5683;

Trkola, A., T. Dragic, J. Arthos, J. Binley, W.C. Olson, G.P. Allaway, C. Cheng-Mayer, J. Robinson, P.J. Maddon and J.P. Moore. 1996. CD4-dependent, antibody sensitive interactions between HIV-1 and its co-receptor CCR-5. Nature 384: 184-187;

Vijh-Warrier, S., A. Pinter, W.J. Honnen and S.A. Tilley. 1996. Synergistic neutralization of human immunodeficiency virus type 1 by a chimpanzee monoclonal antibody against the V2 domain of gp120 in combination with monoclonal antibodies against the V3 loop and the CD4-binding site. J. Virol. 70: 4466-4473;

Wu, L., G. LaRosa, N. Kassam, C.J. Gordon, H. Heath, N. Ruffing, H. Chen, J. Humblias, M. Samson, M. Parmentier, J.P. Moore and C.R. Mackay. 1997. Interaction of chemokine receptor CCR5 with its ligands: multiple domains for HIV-1 gp120 binding and a single domain for chemokine binding. J. Exp. Med. 186: 1373-1381;

EXAMINER

DATE CONSIDERED

^{*}EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

U.S. Department of Commerce Patent and Trademark Office

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Atty. Docket No. Serial No. 57906-E JPW/AJD/BWSL

10/763,545

Applicant(s)

W. C. Olson and P. J. Maddon

Filing Date January 23, 2004 Art Unit

							U	.S.]	PATENT DO	OCUMENTS			
Examiner Initials	Exh No.		Doc	ume	nt N	umb	er		Date	Name	Class	Subclass	Filing Date If Appropriate
				_	cla 88,9		in			Allaway et al.			06/25/01
		1			l cla 23,3		in			Dragic et al.	-		12/19/02
		08	6	2	7	6	8	4		Allaway et al.			04/02/96
		60	0	1	4	5	3	2		Allaway et al.	-		04/02/96
		08	6	6	3	6	1	6		Allaway et al.			06/14/96
	Oï	THER	R DO	C	UM	EN.	rs (Inc	luding Auth	or, Title, Date, P	ertiner	t Pages, E	tc.)
		Parn	neni	ier,	J.C	. G	luc	kma	n, C. Vita a	Drakopoulou, P and A. Benjouad tion of primary m	. 1998.	Synthetic	full length and
		M. I by h	Hilg num ters	artn an a of g	er, l and gp12	D.D chii 0. S	. H npa Sixio	o, N inze eme	I.S.C. Fung a e monoclona Colloque De	M.E. Racho, T.C and A. Pinter. 19 Il antibodies directs Cent Gardes, p	91. Pote cted ag p. 211-2	ent neutraliz ainst three 216;	zation of HIV-1 distinct epitope
		neut CD4	raliz I-bir	zatio ndin	on o g si	of E	IIV. f gp	-1 b 120	y human mo	cho, T.C. Chou onoclonal antiboo Hum. Retrovirus	dies aga es 80: 4	ainst the V	3 loop and the
	ŀ	Cho	e, H	[., N	1. F	arza	ın, `	Y. S	lun, N. Sulliv	/an, B. Rollins, P	D. Por	nath, L. Wu	, C.R. Mackay,

G. LaRosa, W. Newman, N. Gerard, C. Gerard and J. Sodroski. 1996. The beta-chemokine receptors CCR3 and CCR5 facilitate infection by primary HIV-1 isolates. Cell 85: 1135-

1148;

Doranz, B.J., J. Rucker, Y. Yi, R. Smyth, M. Samson, S.C. Peiper, M. Parmentier, R.G. Collman and R.W. Doms. 1996. A dual-tropic primary HIV-1 Isolate that uses fusin and beta-chemokine receptors CKR-5, CKR-3, and CKR-2b as fusion cofactors. Cell 85: 1149-1158;

Deng, H., R. Liu, W. Ellmeier, S. Choe, D. Unutmaz, M. Burkhart, P.D. Marzio, S.Marmon, R.E. Sutton, C.M. Hill, C.B. Davis, S.C. Peiper, T.J. Schall, D.R. Littman and N.R. Landau. 1996. Identification of a major co-receptor for primary isolates of HIV-1. Nature 381: 661-666;

Feng, Y., C.C. Broder, P.E. Kennedy and E.A. Berger. 1996. HIV-1 entry cofactor: functional cDNA cloning of a seven-transmembrane, G protein-coupled receptor. Science 272: 872-877;

Fradd, F. and M.E. Mary. 1989. AIDS Vaccines: An Investor's Guide by Shearman Lehaman Hutton. Page 10 (Fig. 2);

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

U.S. Department of Commerce Patent and Trademark Office

Atty. Docket No. Serial No. 57906-E 10/763,545 JPW/AJD/BWSL Applicant(s)

INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)

Filing Date Art Unit January 23, 2004

W. C. Olson and P. J. Maddon

U.S. PATENT DOCUMENTS

								.0. 1	ALENID	COMENTS						
Examiner Initials	Exh No.		Doc	u me	nt N	umb	er		Date	Name	Class	Subclass	Filing Date If Appropriate			
		60	0	1	9	7	1	5		Allaway et al.			06/14/96			
		08	6	7	3	6	8	2		Allaway et al.			06/25/96			
		08	6	6	5	0	9	0		Allaway et al.			06/14/96			
		60	0	1	9	9	4	1		Allaway et al.			06/14/96			
		08	8	7	4	5	7	0		Allaway et al.			06/13/97			
	O	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)														
		Biar	ichi.	. 19	95.	Sy	nth	etic	peptides fro	M. Panozzo, M. Iom the principle V-1) enhance H	e neutra	lizing don	nain of human			

immunodeficiency virus type 1 (HIV-1) enhance HIV-1 infection through a CD4-

dependent mechanism. Virology 184: 187-196;

Co, M.S., M. Deschamps, R.J. Whitley and C. Queen. 1991. Humanized antibodies for antiviral therapy. Proc. Natl. Acad. Sci. U.S.A. 88: 2869-2873;

Trkola, A., T.J. Ketas, K.A. Nagashima, L. Zhao, T. Cilliers, L. Morris, J.P. Moore, P.J. Maddon and W.C. Olson. 2001. Potent, broad-spectrum inhibition of human immunodeficiency virus type 1 by the CCR5 monoclonal antibody PRO 140. J. Virol. 75: 579-588;

Olson, W.C., G.E. Rabut, K.A. Nagashima, D.N. Tran, D.J. Anselma, S.P. Monard, J.P. Segal, D.A. Thompson, F. Kajumo, Y. Guo, J.P. Moore, P.J. Maddon and T. Dragic. 1999. Differential inhibition of human immunodeficiency virus type 1 fusion, gp120 binding, and CC-chemokine activity by monoclonal antibodies to CCR5. J. Virol. 73: 4145-4155;

Parren, P.W., P.A. Marx, A.J. Hessell, A. Luckay, J. Harouse, C. Cheng-Mayer, J.P. Moore and D.R. Burton. 2001. Antibody protects macaques against vaginal challenge with a pathogenic R5 simian/human immunodeficiency virus at serum levels giving complete neutralization in vitro. J. Virol. 75: 8340-8347;

Lehner, T., C. Doyle, Y. Wang, K. Babaahmady, T. Whittall, L. Tao, L. Bergmeier and C. Kelly. 2001. Immunogenicity of the extracellular domains of C-C chemokine receptor 5 and the in vitro effects on simian immunodeficiency virus or HIV infectivity. J. Immunol. 166: 7446-7455;

Wu, L., W.A. Paxton, N. Kassam, N. Ruffing, J.B. Rottman, N. Sullivan, H. Choe, J. Sodroski, W. Newman, R.A. Koup and C.R. Mackay. 1997. CCR5 levels and expression pattern correlate with infectability by macrophage-tropic HIV-1, *in vitro*. J. Exp. Med. 185: 1681-1691; and

Chen Z., P. Zhou, D.D. Ho, N.R. Landau and P.A. Marx. 1997. Genetically divergent strains of simian immunodeficiency virus use CCR5 as a coreceptor for entry. J. Virol. 71: 2705-2714.

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

U.S. Department of Commerce Patent and Trademark Office

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Atty. Docket No. 57906-E JPW/AJD/BWSL

Serial No. 10/763,545

Applicant(s)

W. C. Olson and P. J. Maddon

Filing Date January 23, 2004 Art Unit

U.S. PATENT DOCUMENTS

Examiner Exh Document Number Date Name Class Subclass													
Examiner Initials	No.		Doc	u me	nt N	umb	er		Date	Name	Class	Subclass	Filing Date If Appropriate
		0.8	8	7	4	6	1	8		Allaway et al.			06/13/97
			Pen	ding)9/7			in			Allaway et al.			11/28/00
			Pen	ding)9/8			in			Allaway et al.			05/09/01
		09	2	1	2	7	9	3		Olson et al.			12/16/98
		60	1	1	2	5	3	2		Olson et al.			12/16/98
		09	4	6	4	9	0	2		Olson et al.			12/16/99
		09	6	6	3	2	1	9		Olson et al.			09/15/00
		60	2	6	6	7	3	8		Olson et al.			02/06/01
		2	00	2/0	1 4	6 4	1 5	5	10/10/02	Olson et al.			
		60	2	8	2	3	8	0		Olson et al.			04/06/01
		2	00	2/0	1 (63	7 4	1	08/08/02	Olson et al.			
		10	0	8	1	1	2	8		Olson et al.		,	02/22/02
		60	3	5	8	8	8	6		Olson et al.			02/22/02
		2	00	3/(0 4	4 4	1 1	l	03/06/03	Olson et al.			
•		2	0 0	3/0	0 9	26	5 3 2	2	05/15/03	Dragic et al.			
		2	00	3/0	2 2	2 8 3	306	5	12/11/03	Olson et al.			
		10	7	6	3	5	4	5		Olson et al.			01/23/04
			Pend	ding			in	'		Allaway et al.			12/13/99
	1	5	9	9	4	5	1	5	11/30/99	Hoxie			
	2	6	7	5	9	5	1	9	07/06/04	Li et al.			
	ļ <u>.</u>												
		l	l										

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Rudikoff, S. Giusti, A. M., Cook, W. D., Scharff M. D., 1982. Single amino acid substitution altering antigen-binding specificity. Proc. Natl. Acad. Sci. 79: 1979-1983

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.